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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,787	03/08/2004	Jeffrey H. Burbank	53951-122	1673

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PROSKAUER ROSE LLP
PATENT DEPARTMENT
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EXAMINER

BIANCO, PATRICIA

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/796,787	Applicant(s) BURBANK ET AL.	
	Examiner Patricia M. Bianco	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/22/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17, 18, 20-22 and 26 is/are allowed.
- 6) ☒ Claim(s) 19 and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Applicant filed an amendment 12/22/05 canceling claims 1-16 and adding claims 17-26.

Claim Objections

Claim 26 is objected to because of the following informalities: Part of claim 26 is confusing; it appears that one or more words are missing between "*filter portion a sterile*" in line 14 of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 recites the limitation "***the in-line pump region***" in line 2 of the claim.

There is insufficient antecedent basis for this limitation in the claim.

Claim 24 recites the limitation "***the sensing step***" in line one of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 25 recites the limitation "***the sensing step***" in line one of the claim. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 23-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-12 of U.S. Patent No.

6,589,482. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are a broader recitation of the invention than that of the issued patent, including all of the same limitations.

The claims of the application claim a method for renal replacement therapy comprising a fluid circuit of first and second sheets of material sealed to form a first fluid pathway and a first chamber free of an air interface, a second panel comprising first and second sheets sealed to form a second fluid pathway and a second chamber being free of an air interface, wherein the first and second panels are arranged in overlapping fashion, attaching a patient to a fluid circuit to access blood, circulating the blood through a blood treatment device, supplying fresh treatment fluid at a rate that waste fluid is withdrawn from the device using the first and second panels to balance the

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volume of removed waste fluid, and measuring the fluid pressure in the first or second pathway using a sensor operatively associated with one of the first or second panels.

The patent claims recite a hemofiltration method comprising a fluid circuit of first and second sheets of material sealed to form a first fluid pathway and a first chamber free of an air interface, a second panel comprising first and second sheets sealed to form a second fluid pathway and a second chamber being free of an air interface, wherein the first and second panels are arranged in overlapping fashion, attaching a patient to a fluid circuit to access blood, circulating the blood through a blood treatment device, supplying fresh treatment fluid at a rate that waste fluid is withdrawn from the device using the first and second panels to balance the volume of removed waste fluid, and measuring the fluid pressure in the first or second pathway using a sensor operatively associated with one of the first or second panels.

Since a broad interpretation of the patent's hemofiltration method includes a renal replacement therapy method as claimed in the application, if a patent was to grant on the pending claims of this application applicant would be granted an unlawful extension of protection beyond the years of the **6,589,482** patent.

Allowable Subject Matter

Claims 17, 18, 20-22, & 26 are allowed.

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Claim 19 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M. Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

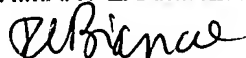
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 4th, 2006

PATRICIA BIANCO
PRIMARY EXAMINER



Patricia M Bianco
Primary Examiner
Art Unit 3761